

Message Text

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21

ACTION EB-03

INFO OCT-01 ARA-10 ISO-00 HEW-01 SCI-03 L-02 COME-00

TRSE-00 AID-05 CIEP-01 CIAE-00 INR-10 NSAE-00 RSC-01

DRC-01 /038 W

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FM AMEMBASSY QUITO

TO SECSTATE WASHDC 2782

INFO AMCONSUL GUAYAQUIL

UNCLAS QUITO 6672

E.O. 11652: N/A

TAGS: BEXP, ECEM, BTRA, EC

SUBJECT: NEW PHARMACEUTICAL REGULATIONS

REF: QUITO A-90 DATED JUNE 29, 1973

1. GOE HAS DRAFTED A NEW LAW REGULATING THE PHARMACEUTICAL INDUSTRY IN ECUADOR WHICH IS READY FOR SIGNATURE AS A DECREE, ACCORDING TO DR. J. GARCIA CONTRERAS, EXPERT ON THE PHARMACEUTICAL INDUSTRY AND UNITED NATIONS ADVISOR TO CENDES (ECUADOREAN CENTER FOR INDUSTRIAL DEVELOPMENT). CONTRERAS THINKS THE PROPOSED REGULATIONS WILL BE VERY DETRIMENTAL TO THE DEVELOPMENT OF THE PHARMACEUTICAL INDUSTRY AND TO THE COMPANIES OPERATING IN ECUADOR. SEVERAL U.S. COMPANIES WOULD BE AFFECTED.

2. MINISTRY OF PUBLIC HEALTH SUBSECRETARY DR. GILBERT BERMEJO V. AND ECONOMISTA MARCOS GUARDERAS, DIRECTOR OF PHARMACEUTICAL PRODUCTS DEPARTMENT, WISH TO TRAVEL TO THE U.S. TO CONSULT WITH THE FOOD AND DRUG ADMINISTRATION AND THE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES TO DETERMINE IF WHAT THEY HAVE DRAFTED IS ADEQUATE. MINISTRY HAS DOUBTS AS TO THEIR PRODUCT. CONTRERAS THINKS THIS MAY BE AN OPPORTUNITY FOR GOE OFFICIALS TO REALIZE THEIR MISTAKES; EMBASSY CONCURS.

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3. ACTION REQUESTED: DEPARTMENT CONTACT FDA AND THE ASSOCIATION OF PHARMACEUTICAL INDUSTRIES FOR SUGGESTIONS AS TO WHOM THEY SHOULD VISIT REGARDING FDA REGULATIONS, QUALITY CONTROL AND RELATED THEMES. SINCE BERMEO AND GUARDERAS WANT TO TRAVEL TO THE U.S. SOONEST, WE WOULD APPRECIATE A PROMPT REPLY.

4. IT WOULD BE HELPFUL IF WE COULD OBTAIN FILMS FOR CONTRERAS' USE IN HIS CONFERENCES. HE STATES HE SAW FOUR PREPARED BY FDA IN SPANISH AND REMEMBERS THE TITLE OF ONE TO BE NO HAY MARGEN PARA ERROR. FILMS SHOULD BE SENT TO EMBASSY VIA INTERNATIONAL MAIL TO ASSURE PROMPT DELIVERY. EMBASSY WILL FORWARD.
BREWSTER

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